APR 3 0 2002

510(k) Summary
as required by 807.92(c)
for Patton Tripol™
Prepared July 5, 2001

K012279

Submitted by: Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, Texas 78746
512 329-0469 Fax 512 328-9113

Contact Person: Michael T. Patton
President

Device Trade Name: **Patton Tripol™** Bipolar Forceps

Common Name: Bipolar Forceps

Classification: DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES

Predicate Devices: **DEXIDE BIPOLAR FORCEPS II** DEVICE (K993055)**, manufactured by United States Surgical, 150 Glover Avenue, Norwalk, CT 06856.

BICOAG COAGULATING FORCEPS (K971565) manufactured by Everest Medical Corp., 13755 First Avenue, North, Suite 500, Minneapolis, MN 55441.

Description of Device:

The **Patton Tripol™** is a forceps that grasps, coagulates, and transects tissue, utilizing electrical current. The device is compatible with available bipolar generators.

Intended Use of Device:

The **Patton Tripol™** is intended for use in open and laparoscopic surgeries where grasping, coagulating, and transecting of tissue is indicated.

Substantial Equivalence to Predicate Device:

The **Patton Tripol™** is substantially equivalent to the Dexide Bipolar Forceps II** Device (K993055), manufactured by United States Surgical, 150 Glover Avenue, Norwalk, CT 06856, and the Bicoag Coagulating Forceps (K971565), manufactured by Everest Medical Corp., 13755 First Avenue, North, Suite 500, Minneapolis, MN 55441.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 0 2002

Mr. Michael Patton
President
Patton Medical Corporation
1000 Westbank Drive, Suite 5A200
Austin, TX 78746

Re: K012279
Trade/Device Name: Patton Tripol Bipolar Forceps
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 26, 2002
Received: March 26, 2002

Dear Mr. Patton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012279

Device Name: Patton Tripol Bipolar Forceps

Indications For Use:

The Patton Tripol is intended for use in open and laparoscopic surgeries where grasping, coagulating, and transecting of tissue is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012279

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)